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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/574,214

04/17/2007

Michihiro Ohnishi

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08/11/2009

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EXAMINER

HANDY, DWAYNE K

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

08/11/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/574,214	Applicant(s) OHNISHI ET AL.	
	Examiner DWAYNE K. HANDY	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/31/06,4/17/07,9/17/07,2/07/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2, 5, 6, 10, 11 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Choong et al. (6,238,909). Choong teaches a method and apparatus for electric field enhanced bioconjugation. The apparatus is best shown in Figures 1-3 and described in columns 6-9. The device includes a substrate (10) having a number of areas for reaction or assay having porous media (20) and electrodes (30) positioned opposite each other with the assay areas in between. Choong teaches placement of one electrode on the substrate surface in column 9, lines 38-41. The Examiner considers the combination of substrate (10) in contact with the lower electrode to be a

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first substrate with a reaction region and first electrode. The Examiner considers the upper electrode to be a second substrate being provided with a common electrode located opposed the first electrode.

4. Claims 1, 2, 5, 6, 10, 11 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsukada et al. (WO 02/066969).

Claims 1, 2, 5, 6, 10, 11 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Tsukada et al. (US 2005/0037348).

Tsukada teaches a method and apparatus for detecting charged substances. The device is best shown in Figures 1- 4 and 10-13 and described in Paragraphs [0058] – [0067]. The device includes a first substrate (21) having a plurality of reaction areas (214) and electrodes (211) opposite a second substrate (22) having a counter electrode (221) that covers most - but not all - of the second substrate.

Inventorship

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 3, 4, 7-9 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsukada et al. (WO 02/066969) in view of Zanzucchi et al. (5,585,069). Tsukada teaches every element of claims 7-9 and 12-14 except for the disc shape and the light source arranged at a position near the first or second electrode. Zanzucchi teaches a microfluidic device for performing a plurality of assays in parallel. The device is best shown in Figures 1, 2, 4A-6A, 7B and 10 and described in columns 4-8. The device is comprised of a multiple micronetworks in parallel on a disc. The

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networks are comprised of reservoirs connected by flow channels extending radially on the disc. Fluid flow is controlled in the networks by spinning the disc. The assays may include use of electrodes and a light source (Figure 6A) to analyze DNA fragments (column 10, lines 6-67). It would have been obvious to one of ordinary skill in the art to combine the disc shape and light detection elements from Zanzucchi with the device of Tsukada. Tsukada teaches a flow through device (Figures 2 and 12) that exposes one electrode in an array to a sample fluid during assay. The use of multiple arrays on a disc would allow for the parallel processing of multiple samples through multiple electrode arrays as in Zanzucchi. One would add the light source and detection elements to analyze the captured DNA fragments as in Zanzucchi.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tanaami and Yasuda teach devices having electrode plates or arrays.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DWAYNE K. HANDY whose telephone number is (571)272-1259. The examiner can normally be reached on M-F 11:00-7:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dwayne K Handy/
Examiner, Art Unit 1797

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797

June 4, 2009